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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,904	01/16/2004	Eric J. Beckman	02-012	1518
29883	7590	06/22/2009		
BARTONY & HARE, LLP 1806 FRICK BUILDING 437 GRANT STREET PITTSBURGH, PA 15219-6101			EXAMINER ROGERS, JAMES WILLIAM	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			06/22/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/759,904

**Applicant(s)**

BECKMAN ET AL.

**Examiner**

JAMES W. ROGERS

**Art Unit**

1618

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05/18/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-69 and 104-112 is/are pending in the application.
- 4a) Of the above claim(s) 12-14,17 and 27-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-11,15,16,18-26,69 and 104-112 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/18/2009 has been entered.

Applicants amendments to the claims filed 05/18/2009 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically a polyurethane is claimed, however a reaction between an isocyanate and an amine group (bioactive agent with group -X which can be an amine) would not form a polyurethane but a polyurea. As evidence applicants only have to consider their own remarks filed 05/18/2009, which on the top of page 15 shows a reaction scheme between an isocyanate, water and an amine, the product is a polyurea (-RNHCONHR-) not a polyurethane (-RNHCOOR-).

**Claims 1,3-11,15-16,18-20,22,25,69,104-11 and 112 are rejected under 35 U.S.C. 102(e) as being anticipated by Beckman et al. (US 7,264,823 B2),** for the reasons set forth in the office action filed 11/30/2007.

**Claims 1,3-4,7-8,12,19,22,27-30,33,69,104-105,108 and 109 are rejected under 35 U.S.C. 102(e) as being anticipated by Woodhouse et al. (US 6,221,997 B1),** for the reasons set forth in the office action filed 11/30/2007.

**Claims 1,3-11,15-16,18-26,69 and 104-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (Biomaterials 21 (2000) 1247-1258) in view of Liptova et al. (Macromol. Symp. 152, 139-150 (2000)) or in view of Woodhouse et al. (US 6,221,997 B1),** for the reasons set forth in the office action filed 11/30/2007.

Applicant's arguments filed 11/03/2008 have been fully considered but they are not persuasive.

Applicants assert that none of the references above describe the reaction between a multifunctional isocyanate with a bioactive agent in water. Applicants assert that water exerts an effect on the reaction in that it acts as a chain extender; therefore the examiner cannot ignore the limitation as this leads to a patentable distinction to the polymers chemical structure. As evidence applicants point to their reaction scheme on page 15 that purports to show the reaction product between an isocyanate, water and an amine and their belief that water is a fundamental aspect in the formation of the polyurethane.

The examiner respectfully disagrees. Firstly it is noted by the examiner as pointed out in the 112 2<sup>nd</sup> paragraph rejection above that the product applicants describe at the top of page 15 is a polyurea not polyurethane. Applicant's arguments seem to revolve around their belief that the chain extender water leads to a patentable difference to the references above. The examiner notes that applicant's claims are drawn to a polyurethane composition formed from the reaction of an isocyanate, water as a chain extender and a bioactive agent. Applicants believe that the reaction with water during the process to make the polyurethane leads to a patentable difference, however as currently amended there is simply no physical characteristic claimed for the polyurethane compositions that would preclude any of the rejections above. Whatever role water plays in the reaction sequence it does not change the chemical structure, the fundamental repeat unit  $(-RNHCOOR-)_n$  of polyurethane. While the limitation detailing the use of aliphatic isocyanates and a bioactive agent containing at least one reactive group must be considered by the examiner since their use changes the structure of the polyurethane, the chain extender, water does not change the chemical structure of the polymer. Chain extenders are generally used in the art to functionalize the end groups of a macromolecule or prepolymer, allowing it to further react with another polymeric block, increasing the overall molecular weight of the polymer. Chain extenders are generally used to increase the molecular weight of a polymer; however applicants do not claim a molecular weight within their own claims that would preclude any of the references above. Thus the only physical characteristic of the polymer that would be affected by the chain extender water is not present within the claims. Furthermore

applicants note at paragraph [0008] within their own specification that Zhang and coworkers used water as chain extenders for the prepolymers, Zhang also states that water is used as a chain extender within the abstract. Also Beckman describes using water in reactions of LDI and glucose to make a foamed material. See col 8 lin 21-55.

Applicants further assert there is no disclosure or suggestion within Zhang that details the reaction of a protein or any other bioactive agent with a multifunctional isocyanate compound and Zhang does not even mention what is meant by incorporation of proteins.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Clearly the examiner noted that Zhang while disclosing the peptide based urethane polymer may allow incorporation of proteins of interest such as cell attachment and/or growth factors but does not give any working examples, which is why the reference was combined with the other two other references in a 103(a) obviousness type of rejection. From the disclosures of Liptova and Woodhouse it would have been obvious to one of ordinary skill in the art that polyurethanes of Zhang could be conjugated to bioactive substances such as peptides and heparin.

### **Conclusion**

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D.

whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618